

Study protocol

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## Improving healthcare consumer effectiveness: An Animated, Self-serve, Web-based Research Tool (ANSWER) for people with early rheumatoid arthritis

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### Abstract

**Background:** People with rheumatoid arthritis (RA) should use DMARDs (disease-modifying anti-rheumatic drugs) within the first three months of symptoms in order to prevent irreversible joint damage. However, recent studies report the delay in DMARD use ranges from 6.5 months to 11.5 months in Canada. While most health service delivery interventions are designed to improve the family physician's ability to refer to a rheumatologist and prescribe treatments, relatively little has been done to improve the delivery of credible, relevant, and user-friendly information for individuals to make treatment decisions. To address this care gap, the **Animated, Self-serve, Web-based Research Tool (ANSWER)** will be developed and evaluated to assist people in making decisions about the use of methotrexate, a type of DMARD. The objectives of this project are: 1) to develop ANSWER for people with early RA; and 2) to assess the extent to which ANSWER reduces people's decisional conflict about the use of methotrexate, improves their knowledge about RA, and improves their skills of being 'effective healthcare consumers'.

**Methods/design:** Consistent with the International Patient Decision Aid Standards, the development process of ANSWER will involve: 1.) creating a storyline and scripts based on the best evidence on the use of methotrexate and other management options in RA, and the contextual factors that affect a patient's decision to use a treatment as found in ERAHSE; 2.) using an interactive design methodology to create, test, analyze and refine the ANSWER prototype; 3.) testing the content and user interface with health professionals and patients; and 4.) conducting a pilot study with 51 patients, who are diagnosed with RA in the past 12 months, to assess the extent

to which ANSWER improves the quality of their decisions, knowledge and skills in being effective consumers.

**Discussion:** We envision that the ANSWER will help accelerate the dissemination of knowledge and skills necessary for people with early RA to make informed choices about treatment and to manage their health. The latest in animation and online technology will ensure ANSWER fills a knowledge translation gap, focusing on the next generation of people living with RA.

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## Background

Treatment approaches for RA have changed drastically in the last decade. In the old "pyramid" approach, patients were treated with non-steroidal anti-inflammatory drugs (NSAIDs) without DMARDs until evidence of joint damage appeared. Nowadays, DMARD is used early (i.e., within three months of onset) and consistently, with the aim of eradicating inflammation and preventing joint damage [1-3]. The short-term clinical efficacy of various DMARDs at reducing disease activity, improving physical function and retarding radiographic progression has been demonstrated in RCTs and the subsequent systematic reviews [4-6]. Long-term epidemiological studies have also shown that earlier and more consistent treatment with DMARDs reduces joint destruction and leads to better long-term physical function [7-9]. Delays as brief as three months in starting DMARDs have been associated with poorer long-term outcomes, including greater physical disability [10-12] and joint damage [13-15], and less chance of remission [16]. The evidence suggests that there is a window of opportunity, early in the disease, to successfully control the disease progression; however, only a minority of people with RA used DMARDs after a recent diagnosis [17].

Patients' decisions on medication use can be affected by their concerns about side effects [18]. For example, with methotrexate, a commonly used DMARD, the side effects may include diarrhoea, lung infections, headache, nausea, heartburn, rash, and high liver enzyme, although the occurrence is rare [4,5]. About 10% of patients stopped taking methotrexate due to side effects; however, 9% also stopped the placebo due to the same reasons [4]. Currently, most information on arthritis medications is provided in the written format, which can be challenging especially for people with low literacy. However, while most health service delivery interventions are designed to improve the family physician's ability to refer to a rheumatologist and prescribe medications [19-21], relatively little has been done to improve the delivery of credible, relevant, and user-friendly information for individuals to make treatment decisions.

To address this care gap, we propose to develop and evaluate an **Animated, Self-serve, Web-based Research Tool** (ANSWER) to assist people with a new RA diagnosis to

make decisions about using methotrexate. The innovative aspect of ANSWER is its built-in storyline that illustrates common situations that people experience when making decisions about their treatment, and demonstrates the attributes required for effective management of their healthcare. Our specific objectives are to: 1) develop ANSWER for people with early RA; and 2) assess the extent to which ANSWER reduces people's decisional conflict, improves their knowledge about RA, and improves their skills of being 'effective healthcare consumers'.

## Previous research

The development of ANSWER is based on the findings from three projects funded by the Canadian Institutes of Health Research (CIHR; [http://webapps.cihr-irsc.gc.ca/funding/Search?p\\_language=E&p\\_version=CIHR](http://webapps.cihr-irsc.gc.ca/funding/Search?p_language=E&p_version=CIHR)): 1) the RA Care Gaps project [18]; 2) the ERAHSE (Early RA Help-Seeking Experience) project; and 3) the Effective Consumer project [22].

The RA Care Gaps project surveyed 1,822 patients in British Columbia (BC) and found that the main reasons for not using DMARDs included a lack of physician advice (45%), fear of side effects (26%), preference to avoid medications (24%), and perceived lack of need (23%) [18]. These findings were confirmed by ERAHSE using qualitative interviews of 38 people with newly diagnosed RA (12 months or less). The preliminary data analysis identified common themes about challenges to making treatment decisions or negotiating the healthcare system [23], including: 1) incomplete discussions about benefits and risks of treatment options during medical visits, making it impossible to make an informed choice; 2) frustration with not being heard by the physician, resulting in discontinuation of medical visits by some participants; and 3) frustration with not knowing which, and how to access, health resources even if they knew disease-related information was available.

Another recurring theme identified in ERAHSE was the complex interplay of factors that affected people's treatment decisions. These included the disease characteristics (e.g., insidious versus sudden onset), people's health beliefs, their knowledge and attitudes toward RA and treatments, and their past experience with medications and health professionals. Underlying these factors was the

profound feeling of ambivalence that is marked, on one hand, by an aversion to medications because of the anticipated side effects, and on the other, by a fear of the potentially crippling effects of an uncontrolled disease. The circumstance in which people decided to use or not use medications appeared to be influenced by the nature of their symptoms in the context of daily life.

Concerns about side effects were part of the background knowledge that many participants brought to their initial medical consultations. It appeared that these concerns were likely to remain unresolved if they left the doctor's office with unanswered questions or unaddressed concerns about the treatment. This might explain why those who stayed on medications reported having good rapport with their rheumatologists and/or family doctors, and that they were more engaged in communicating and making treatment decisions with their doctors. Interestingly, health education messages, such as those that tout the importance of starting DMARDs within a certain 'window of opportunity' appeared to motivate some ERAHSE participants to begin treatment. These findings highlight the importance of good patient-physician partnerships in people's decisions to use/continue medications, and provide the necessary context for the development of a decision-making tool that mirrors the typical challenges and situations in which people make their treatment choices.

#### **What are the attributes of an 'effective healthcare consumer'?**

Most patient education initiatives aim to empower people with arthritis to become active participants in their healthcare decisions (i.e., 'effective consumers'). The concept of "effective consumer", developed by Tugwell et al. [22] posits that individuals can acquire knowledge and skills that empower them to manage their health and to become more effective users of healthcare resources. Through extensive interviews and collaborations with arthritis patient groups, five essential attributes of effective healthcare consumers were identified, including the ability to: 1) use health information; 2) clarify personal priorities for disease management; 3) communicate with health professionals; 4) negotiate roles and take control; and 5) make decisions and take action [22,24]. It has been argued that these attributes can be used to guide the development of the next generation of patient education/self-management initiatives [25].

Another major contribution of the effective consumer project was the EC-17 scale [24]. Unlike traditional measures in studies of self-management interventions, which focus on RA outcomes (e.g., pain, joint counts, self-efficacy, life satisfaction, coping, social function) [26], the EC-17 evaluates the person's ability to participate in his/her healthcare. The psychometric properties of the EC-17

are currently being tested in self-management interventions [24]. In the ANSWER project, we will apply the effective consumer attributes to design the knowledge and skills learned by the main character portrayed in the ANSWER storyline, and will use the EC-17 scale in the pilot evaluation.

#### **Methods/design**

ANSWER will be developed based on the rigorous criteria outlined in the International Patient Decision Aid Standards [27,28], and through a collaboration of health researchers, computer animation experts and trainees, and people with RA. Using an iterative design approach, we will create an animated decision aid for users with low health literacy and low-to-average computer skills. Because our main audience is people recently diagnosed with RA, we will focus on creating scenarios that are less threatening to the users (e.g., starting the story in the home and work environment rather than in a hospital). ANSWER will be structured with dual components: stories acted by the main animated character and an interactive decision-making component.

We will adapt Jibaja-Weiss et al.'s Edutainment Decision Aid Model [29], which consists of three inter-linked components: the story; the learning media; and the graphical user interface by which the user interacts with the story and learning media. At different points throughout the story, the user will be required to make decisions. Decision support information (i.e., the risk and benefits of treatment options) will be embedded in both the story and learning media. The animated character will model the skills necessary to be an effective consumer.

The development process of the ANSWER tool involves: 1) writing a brief interactive narrative with multiple storylines for the animated segments and content for the learning segments; 2) refining the storyline and learning segments; and 3) defining the linkages between the story and the learning segments. The storyline will be based on the ERAHSE qualitative interviews. Once the user completes the program, a tailored summary will be generated describing his/her health information, treatment choices, initial decisions made, and concerns about the treatments he/she wishes to discuss with the doctor.

The decision support component will focus on the use of methotrexate. ANSWER will be developed based on the current systematic reviews and clinical practice guidelines about methotrexate [30,31], including the probability for favourable clinical outcomes and side effects. To enable use by computer novices, we will design the graphical user interface of the decision aid such that it resembles a computer game that allows user interaction to enhance the

uptake of information. All written content and instructions will be fully narrated.

We will test the content and user interface of the ANSWER prototype with five people from each of the following groups: 1) rheumatologists/arthritis nurses; 2) allied health professionals; 3) people with RA diagnosed  $\leq$  3 months; 4.) those with RA  $>$  3 months. The time needed to complete the tool will be tracked. After the testing section, participants will be interviewed to obtain comments about the content, presentation and user friendliness. The tool will be refined based on the users' comments.

#### **Pilot study**

A prospective pre-post design will be used in the online pilot study. We will invite people with RA across Canada to participate. Eligible individuals will be those who: 1) are diagnosed with RA; 2) are candidates for methotrexate as indicated by their rheumatologists and have not initiated treatment; and 3) have Internet access. Participants will be recruited from two sources: 1) the Mary Pack Arthritis Program; and 2) patient/consumer groups, including the Canadian Arthritis Patients Alliance and JointHealth. In addition, we will post the information on the Arthritis Research Centre of Canada website. Individuals who are interested may contact the research assistant who will provide details about the study, screen for eligibility and obtain informed consent.

Participants will receive a username and password via e-mail to access the ANSWER testing webpage. They may complete the program at their own pace, and may sign off and return later. At the end of the program, ANSWER will produce a one-page summary for the individual to discuss with his/her rheumatologist/family physician, and then make a decision about the treatment.

#### **Outcome measures**

Participants will be asked to complete the following measures online before and after using the ANSWER: 1) the Decisional Conflict Scale (low literacy version; primary outcome); 2) the EC-17 Scale; and 3) the ACREU (Arthritis Community Research & Evaluation Unit) RA Knowledge Questionnaire. The Decisional Conflict Scale measures personal perceptions of uncertainty in choosing options, factors contributing to uncertainty, and effective decision making [32]. The low literacy version has 10 questions and three response categories. Both internal consistency and test-retest reliability exceed 0.78. In studies of decision aids for non-RA interventions, the effect sizes range from 0.4 to 1.2 [32-34].

The RA Knowledge Questionnaire comprises 31 items covering seven domains: prognosis, coping strategies, pain management, exercise, medication, joint protection,

and energy conservation [35]. The questionnaire has demonstrated internal consistency (Cronbach's  $\alpha = 0.76$ ), test-retest reliability ( $r = 0.91$ ), and content and construct validity [35]. Also, participants will complete the following measures at baseline: 1.) Health Assessment Questionnaire (HAQ; a validated measure of health status of people with RA); 2.) RADAI (RA Disease Activity Index); and 3.) comorbid conditions and demographic characteristics. The scores of HAQ and RADAI, and the comorbid conditions will be summarized on the one-page summary for participants.

#### **Sample size and analysis**

Based on previous before-and-after studies using the Decisional Conflict Scale, we estimated a difference of 0.3 and a standard deviation of 0.6 [32,33]. This yields a sample size of 43 ( $\alpha$ -level = 0.05; 90% power). Assuming that 15% of eligible participants do not complete the task and/or the outcome measures, 51 participants will be needed. Exploratory analysis using paired t-tests will be done to evaluate the changes in the three outcome measures. Descriptive analysis will be used to summarize participant characteristics and comorbid conditions.

The ANSWER protocol has been approved by the University of British Columbia Behavioural Research Ethics Board (Application number: H09-00898).

#### **Limitations**

Although the selected outcome measures will capture changes in outcomes from the patient's perspective, we will not be able to determine if the ANSWER affects the physician's participation in shared decision-making, or if it improves patient-physician communication during the clinical visit. However, owing to the resources required to collect data from the study participant's physician(s), it is prudent to first demonstrate the value of this new tool for the users in a small pilot study. Favorable results from this study will provide the justification and background data for a full-scale randomized controlled trial that evaluates the effectiveness of ANSWER from the perspectives of both patients and physicians.

#### **Discussion**

This innovative project combines the expertise from six disciplines: health services research (LCL, CLB, DL, DS, PT), clinical research (DL), social science (PA, SC, AFT), information science (JM), knowledge translation (LCL, PT, KH, JM) and digital media (GS), and three stakeholders groups: patients/consumers (Canadian Arthritis Patient Alliance, JointHealth, and Arthritis Research Centre of Canada – Consumer Advisory Board), the clinical community (Mary Pack Arthritis Program), and a non-profit arthritis organization (The Arthritis Society).

A multi-sector, inter-disciplinary team has been assembled to create and evaluate the ANSWER. Guided by Graham's Knowledge-to-Action process [36], this knowledge translation project will directly address one of the recommendations of the 2005 Summit on Standards for Arthritis Prevention and Care that, "Every Canadian with arthritis must have access to accurate information and education on arthritis that meet a defined set of criteria and are appropriate to their age and stage of disease" [37] We envision that the ANSWER will help accelerate the dissemination of knowledge and skills necessary for people with early RA to make informed choices about treatment and to manage their health.

### Competing interests

The authors declare that they have no competing interests.

### Authors' contributions

The study was conceived by LCL, PA, AT and CLB. All authors contributed to the development of the research protocol. LCL is the principal applicant and PA is the decision-maker co-principal applicant. Writing of the manuscript was led by LCL and all authors approved the final version.

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